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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,379	04/16/2004	Marco Cavaleri	892,280-137	4823

34263 7590 06/08/2005

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EXAMINER	
PESELEV, ELLI	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,379	CAVALERI ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 09 May 2005.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 24-59 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 24-59 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The disclosure is objected to because of the following informalities: the U.S. Serial Numbers are incomplete on page 12 of the specification, paragraph 0046 and page 18 of the specification, paragraph 0071.

Appropriate correction is required.

Claims 32, 34-36 and 38-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terminology "the initial dose is about 1500 mg" (claims 32 and 50), "the initial dose is about 800 mg" (claims 34 and 52), "the initial dose is about 500 mg" (claims 35 and 53), "each subsequent dose is about 400 mg to about 1000 mg" (claims 36 and 54), "each subsequent doe is about 400 mg" (claim 38 and 56), "each subsequent dose is about 250 mg" (claims 39, 57 and 59), "each subsequent dose is about 200 mg" (claims 40 and 58), "the initial dose is about 1000 mg and the amout of each subsequent dose is about 250 mg: (claims 41 and 59", "the initial dose is about 200 mg to about 1500 mg and the amount of each subsequent dose is about 200 mg to about 1500 mg" (claim 42), "the initial dose is about 800 mg" (claim 52), "complicated skin and soft tissue infection" (claims 30 and 48) and "uncomplicated skin and soft tissue infection" (claims 31 and 49) is not disclosed or suggested by the specification as originally filed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,900,175 for the reasons set forth in the Office Action of January 12, 2005.

Claims 24-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-24, 28-32, 37-43 and 54-66 of copending Application No. 10/828,439 for the reasons set forth in the Office Action of January 12, 2005.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 24-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of copending Application No. 10/828,483 for the reasons set forth in the Office Action of January 12, 2005.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed May 9, 2005 have been considered but have not been found persuasive.

Since the Terminal Disclaimers have not been filed at the time of the present Office Action, the above stated rejections have not been overcome.

Claims 24-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Dalbavancin tested for soft tissue infections" (2001) or "Molecule of the Month V-Glycopeptide" (2000) for the reasons set forth in the Office Action of January 12, 2005.

Applicant's arguments filed May 9, 2005 have been considered but have not been found persuasive.

Applicant contends that contrary to the conventional wisdom, applicant has unexpectedly discovered a dramatic increase in efficacy by administering doses of Dalbavancin at intervals of about 5-10 days as set forth in Tables 4 an5 on pages 33 and 35 of the specification. Tables 4 and 5 have been considered. The Tables compare the efficacy of a single dose administration of Dalbavancin at a dosage of 1100 mg and a two dose administration of Dalbavancin, wherein the first dose is 1000 mg and the second dose is 500 mg i.e. the data presented in said Tables is limited to the case wherein the first dose is two times larger that the second dose. However, note that claim 24 encompasses a case wherein the first dose is 500 mg and the second dose is 2500 mg i.e. wherein the first dose is five times less than a second dose. Also, claim 42 encompasses a case wherein the first dose is 200 mg and the second dose 1500 mg i.e. wherein the second dose is more than seven times larger than a first dose. Applicant has not presented any evidence of the improved efficacy in cases wherein the

second dose is four times less than a first dose, is the same as the first dose or larger than the first dose. Therefore, the claimed methods are still deemed prima facie obvious over the art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

ELLI PESELEV
PRIMARY EXAMINER
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